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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/813,423
Filing Date: March 30, 2004
Appellant(s): CONNORS ET AL.

Robert K. Fergan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 31, 2007 appealing from the Office action mailed March 20, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP 769306	Engelson	4-1997
US 6,652,472	Jafari et al.	7-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

- A. Claims 1, 2, and 5 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Engelson (EP 769306).**

Engelson ('306) teaches a method for making a wire guide, therein providing a mandrel having a proximal portion and a distal portion (col. 5, line 10-16). The said wire guide has a permanent, spray-applied first coating of polytetrafluoroethylene, low coefficient of friction polymer surface, majority of its length located proximally by spraying the coating over the mandrel having a proximal portion and distal portion. Engelson does not take any extra effort such as masking the distal portion in order to coat solely over proximal portion, thus some of the first coating would inherently be sprayed on the distal portion. In addition, the said distal portion of the mandrel can be connected to a radio-opaque coil (col. 5, line 19-20).

Engelson further teaches a procedure for pretreating the more-distal portion of the guide wire prior to receiving a subsequent coating, e.g. the tie coating and third coating, of a lubricious, biocompatible and hydrophilic polymer is via the use of plasma stream to deposit a hydrocarbon or fluorocarbon layer on the mandrel (col. 10, line 10-15). The procedure is as follows: the guide wire mandrel is placed in a plasma chamber and cleaned with oxygen plasma etch, e.g., to clean the distal end of the mandrel which would remove the first coating applied to the distal end due to overspray from the distal portion of the mandrel because it is known to use an oxygen plasma etch to remove a fluorocarbon material (i.e. the first coating), the guide wire mandrel is then exposed to a

hydrocarbon plasma to deposit a plasma-polymerized tie layer, e.g. the second coating layer, thereon.

Engelson teaches that the suitable material for such tie layer (col. 9, line 28-46) may be strong and flexible polymer such as polyurethane, which provides a sub-structure to the third layer coating.

The lubricious hydrophilic third coating layer is applied over the said second coating layer and the suitable material for third layer is polyvinylpyrrolidone (col.8, line 44), wherein the third coating layer comprises a surface that allows for easy maneuverability of the wire guide (col.4, line 55-56)

As for claims 2 and 4:

Engelson teaches that the lubricious hydrophilic third coating is preferably produced using generally simultaneous solvent removal and cross-linking operation (col.8, line 49-51). The solvent removal procedure takes place in a heating chamber of the temperature of 750-1000C (col. 9, line 3-4). The Surface of the third coating is maintained up to the glass transition temperature (Tg) of the underlying layers. Therefore, the lubricious hydrophilic surface coating is polished and allows for easy maneuverability of the wire guide through a vascular anatomy (col. 4, line 55-58).

B. Claim 3 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson (EP 769306) in view of Jafari et al. (US 6,652,472).

Engelson teaches that which is disclosed in above. The distal portion of the mandrel in the teaching of Engelson is tapered (col. 5, line 41), however, Engelson is

silent concerning forming the tapered distal portion in the same time of removing the first coating layer by a etching process thereon.

Jafari et al. teach a method for making a wire guide, therein providing a mandrel having a proximal portion and distal portion (col. 2, line 29-37). The said mandrel is coated with a lubricious coating such as Teflon, which extends the length of the proximal portion. The distal section has tapered flexible segments (col.3, line 59), which is also provided with a different lubricous coating (col. 4, line 12). Engelson teaches a centerless grinder may be used to grind the tapers or other means such as chemical means, e.g. etching, can be used to form the tapered segments in the distal portion of said mandrel (col. 5, line 32-39). Since both Engelson and Jafari et al. teach a tapered segment in the distal portion of the guide wire, Jafari et al provide the success of forming the tapered segment by chemical etching or mechanical grinding, therefore it would have been obvious to one of ordinary skill in the art to use the teaching of Jafari et al. in the method of Engelson to remove the first coating on the distal portion in the same time to form the tapered segment in distal portion of said guide wire. One would be able to combine the processes of cleaning and tapering the distal portion in one and to create a flexible and maneuverable guide wire tip cost-effectively.

(10) Response to Argument

A. The 35 USC 102 rejection of claims 1, 2, 4, and 5 using Engelson

Appellant's Arguments

Appellant notes that the Engelson reference does not teach each and every limitation of the independent claims 1 and 5 either expressly or inherently.

"...*Engelson* does not disclose the steps of applying a first coating to a mandrel and removing the first coating from the distal portion of the mandrel." (see paragraph bridging pages 7-8 of the Appeal Brief of October 31, 2007)

The Appellant further states the teachings of the Engelson reference and the limitations which are not taught

"Contrarily, *Engelson* teaches the application of a first coating solely over the proximal region of a mandrel rather than over both a proximal portion and a distal portion the mandrel. As such, *Engelson* fails to teach removing the first coating from the distal portion." (see paragraph 2 on page 4 of the Appeal Brief of October 31, 2007).

Appellant goes on to state how the Examiner's reasoning for applying the Engelson reference to independent claims 1 and 5 using inherency reference is in valid and that rationale and evidence must be provided to show inherency. The Appellant further states

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result characteristic. *Id.* To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in that thing described in the reference, and that it would be so recognized by persons of ordinary skill. Here, the Examiner has not provided evidence or rationale that the first coating would be sprayed on the distal portion. Rather, the Examiner simply relies on *Engelson's* lack of disclosure to solely coat the proximal portion of the guide wire. The mere possibility that coating the distal portion may occur based on an absence of a masking step is no sufficient" (see paragraph 1 on page 5 of the Appeal Brief of October 31, 2007)

In regards to the limitation of applying the coating to the entire mandrel, both the proximal and distal region, the Appellant further states that the reasoning of the Examiner is improper

"...the guidewire typically has a total length typically between about 50 to 300 centimeters" and the relatively more flexible distal section (106) extends for 3 to 45 centimeters or more of the distal end of the guide wire (100)...Although the Examiner

may be correct that the first coating in *Engelson* is applied on the majority of the length of the mandrel, it is only because the majority of the length is its proximal section 102 while merely 3 to 45 centimeters encompasses the length of the more flexible distal section 106 of the guide wire 100." (see the first full paragraph on page 6 of the Appeal Brief of October 31, 2007).

"... although *Engelson* may or may not take any extra effort such as masking the distal portion in order to coat solely over the proximal portion thereof, *Engelson* still fails to teach applying a first coating over the distal portion of the mandrel. Any coating of the non-hydrophilic lubricious polymer on the distal portion would be by mere accident and is not taught in *Engelson*." (see the second full paragraph on page 6 of the Appeal Brief of October 31, 2007)

The appellant argues how the *Engelson* does not teach the limitation of removing the first coating from the distal portion because for one the reference does not teach applying the first coating to the distal end of the mandrel and furthermore because the pretreatment/ cleaning process of *Engelson* refers to

"...cleaning process to prepare the metal surface of the wire guide core, for the application of a hydrophilic polymer rather than a process for removing a first coating from the distal portion of the mandrel...the procedure is as follows the *wire guide core* is placed in the plasma chamber and cleaned with an oxygen plasma etch. The *wire guide core* is then exposed to a hydrocarbon plasma to deposit a plasma polymerized tie layer on the layer guide core to complete the pretreatment. As such it is clear that the oxygen plasma etch cleaning happens prior to the deposition of either the tie layer 110 or the hydrophilic layer 109....As such, it can be understood that the steel surface of the wire guide core is what is being cleaned by the oxygen plasma etch, rather than an applied coating being removed by the oxygen plasma etch" (see the paragraph bridging pages 7-8 of Appeal Brief of October 31, 2007).

The Examiner's Response

The Examiner has reviewed appellant's arguments; however, her position that the claimed invention is anticipated is maintained.

On page 4 of the Appeal Brief of October, 31, 2007, the Appellant states that "[c]ontrarily, *Engelson* teaches the application of a first coating **solely** over the proximal region of a mandrel rather than over both a proximal portion and a distal portion of the

mandrel." It is the Examiner's position that Engelson does teach that the "guidewire 100... which has a more proximal region ("02) having a permanent, spray applied coating (103) of a fluorocarbon polymer ... applied directly to the core wire (104) and a more distal region (106) adjacent to the more-proximal region (102)" (col. 4, lines 8-16), it should be further noted that this section discusses the final product which is produced by the method taught by Engelson this does not provide method steps for how the coatings are applied to the core wire.

In response to the Appellant's arguments with respect to the inherency that a portion of the first coating (non hydrophilic material) will be applied to the distal end of the guide wire due to there not being a teaching of masking the core wire while spraying to prevent such from occurring. It is the Examiner's position that appropriate evidence of inherency has been presented because no where in the disclosure of Engelson is there any indication of a masking step in the process of spraying the non hydrophilic coating furthermore it is also known in the coating art that when spray coating an object in particular when a certain portion of an object is desired to be coated there are two ways in which this can be achieved (1) by masking off the area which is not intended to receive the coating or (2) by applying the coating then removing the coating from undesired portions. In the process of Engelson the desired portion to be coated is the proximal end however, Engelson does not teach a masking of the distal end therefore the non hydrophilic material would inherently coat onto the distal end because as stated above, the only way to spray coat a portion of an object is to mask off the object or remove the undesired coating in subsequent steps.

In regards to the Appellant arguments that the "mere possibility that the coating the distal portion may occur is based on an absence of a masking step is insufficient."

(page 5 of the Appeal Brief of October 31, 2007). The Examiner would disagree that the coating of the distal portion is a "mere possibility" because as stated above it is known in the spray coating art that when spray coating, applying a liquid in a fine mist to an object, any portion of the objection will receive or be coated with the mist unless the object is masked or after the coating is applied any undesired portions are removed.

Also, since there is no masking step provided the next step would be to remove the non hydrophilic coating from the distal end because in the **final product** the fluorocarbon polymer layer is on the proximal end of the wire core.

In response to the Appellant's arguments that "the mere possibility that a subsequent cleaning would remove any undesired coating is not sufficient. The Examiner has not made it clear how a cleaning procedure would inherently remove any undesired coating on the distal portion." (page 6 of the Appeal Brief of October, 31, 2007), the Examiner would disagree that the cleaning is a "mere possibility" as addressed above, the only way to achieve coating a desired portion of an object using spray coating is to either mask off the area or apply the coating and in a subsequent step remove the coating.

The Appellant's arguments to the Examiner's reasoning for stating that Engelson teaches the removal of the first coating from the distal portion are not persuasive. The Appellant states that "[t]he procedure to remove the first coating from the distal portion of the mandrel the Examiner refers to is merely a cleaning process to prepare a metal surface of the wire guide core, for the application of a hydrophilic polymer rather than a process for removing a first coating from the distal portion of the mandrel." (see page 7 of the Appeal Brief of October 31, 2007). The Appellant further states on page 7, that

"[a]s such, it is clear that the oxygen plasma etch cleaning happens prior to the deposition of either the tie layer 110 or the hydrophilic layer 109."

It is the Examiner's position that the step of oxygen plasma treating the wire guide core prior to the application of the tie layer or the hydrophilic layer (which correspond to the second coating and third coating in claim 1 of the present application) would inherently result in the removal of the spray coated first non hydrophilic coating applied because as stated above, this layer needs to be removed from undesired portions (distal end) of the wire core furthermore, since the material being applied is a fluorocarbon it is well known that an oxygen etch would remove such a material from the distal end of the wire core. This step would prepare the wire core by cleaning so that the subsequent tie and hydrophilic layer is applied to the wire core.

B. The 35 USC 103 rejection of claim 3 using Engelson in view if Jafari (US 6652472).

Appellant's Arguments

Appellant argues that Jarafi does not teach the elements of independent claim 1 missing from the Engelson reference such as the teaching of applying the first coating to the proximal and distal end and further removing the first coating from the distal end. Futhermore, the Appellant states

"[s]ince claim 3 generally depends from claim 1, the reasons given above in support of claim 1 are equally applicable to claim 3." (see last paragraph on page 8 of Appeal Brief of October 31, 2007).

Examiner's Response

The Examiner has reviewed the appellant's arguments; however, her position that the claimed invention is obvious is maintained.

The arguments addressing the lack of teaching in the primary reference Engelson with respect to independent claim 1 were addressed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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